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Safety and effectiveness of the INCRAFT AAA Stent Graft for endovascular repair of abdominal aortic aneurysms

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Objective: This study evaluated the 2-year safety and effectiveness of the European First-in-Human INNOVATION trial for the INCRAFT AAA Stent Graft system (Cordis Corp, Bridgewater, NJ), an ultra-low-profile device for the treatment of abdominal aortic aneurysms.

Methods: From March 2010 to June 2011, the INNOVATION prospective multicenter trial involving six centers in Europe enrolled and treated 60 asymptomatic patients (95% male; mean age, 74.4 ± 6.9 years) with the INCRAFT System. Main inclusion criteria included proximal aortic neck length of 15 mm or more with a diameter up to 27 mm; distal iliac landing zones with a length greater than 10 mm and a diameter between 9 and 18 mm; and aortic bifurcation >18 mm in diameter and access vessels large enough to accept the 14F outer diameter of the delivery system. The primary end point was technical success at 1 month; 2-year safety end points included the absence of device- or procedure-related major adverse events, absence of type I or III endoleaks, and maintenance of device integrity through 2 years of follow-up. Study oversight was provided by a Data Safety Monitoring Board with event adjudication by a Clinical Events Committee and imaging analysis by an independent core laboratory.

Results: Of 60 successfully treated patients, two did not come back for their 1-month evaluation but remained enrolled in the study; 56 were evaluated at 1 year and 52 at 2 years. Of the 58 patients, 56 met the 1-month primary safety and effectiveness end point (97%; 95% confidence interval, 88%-100%). All patients were free from aneurysm enlargement through 2 years. There were no type I or III endoleaks at the 2-year time point. All-cause mortality at 2 years was 11.5%, and no death was device or procedure related. In total, three patients required a postprocedure intervention, two to repair a type I endoleak and one for limb occlusion. Core laboratory evaluation of the postoperative imaging studies documented absence of endograft migration and stent fractures in all patients.

Conclusions: The INCRAFT AAA Stent Graft System provides a durable solution for patients with abdominal aortic aneurysms, with a low frequency of device-related events through 2 years of follow-up.

Standard endovascular treatment of abdominal aortic aneurysms in patients with very short proximal necks using the Endurant stent graft

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Objective: This study evaluated and compared the midterm results of endovascular aortic aneurysm repair with the Endurant (Medtronic Inc, Santa Rosa, Calif) stent graft system in off-label use in patients with short (<10 mm) proximal aortic necks and in patients treated according to device-specific instructions for use.

Methods: This was a case-control (2:1) single-center retrospective analysis of prospectively collected data performed between September 2008 and December 2012. Analysis identified 19 elective patients with short (<10 mm) proximal necks and mild angulations (≤45°) treated with the Endurant stent graft and 38 patients matched for age, sex, and aneurysm diameter with proximal aortic necks â¥10 mm in length who met the instructions for use. End points included technical and clinical success and freedom from any secondary intervention, any type of endoleak, and aneurysm-related death.

Results: The short-neck group was a mean ± standard deviation age of 71.7 ± 8.9 years, 84% were men, and their mean infrarenal aortic neck length was 6.1 ± 1.2 mm. Mean suprarenal and infrarenal angles were 110° ± 10.4° and 170° ± 15.4°, respectively. Aortic neck diameters were similar between the groups (26.6 ± 3.8 vs 25.7 ± 3.7 mm; P = .36). Primary technical success was achieved in all cases. Off-label patients were more likely to require additional proximal cuff deployment to successfully obtain a seal (21% vs 3%; P = .04). The two patient groups were similar in rates of perioperative mortality, morbidity, and complications. Mean follow-up of 24 ± 12 months revealed no differences in clinical success, freedom from reintervention, and aneurysm-related death. No type I endoleaks were observed in either group during the follow-up period.

Conclusions: The Endurant stent graft system applied off-label in patients with very short aneurysm necks (<10 mm) with mild angulation showed acceptable treatment results. These midterm results might suggest its use in carefully

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selected patients with very short neck anatomy. Long-term data are needed to verify the observed durability of the Endurant stent graft.:

The Abdominal Aortic Aneurysm Statistically Corrected Operative Risk Evaluation (AAA SCORE) for predicting mortality after open and endovascular interventions

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Background: Accurate adjustment of surgical outcome data for risk is vital in an era of surgeon-level reporting. Current risk prediction models for abdominal aortic aneurysm (AAA) repair are suboptimal. We aimed to develop a reliable risk model for in-hospital mortality after intervention for AAA, using rigorous contemporary statistical techniques to handle missing data.

Methods: Using data collected during a 15-month period in the United Kingdom National Vascular Database, we applied multiple imputation methodology together with stepwise model selection to generate preoperative and perioperative models of in-hospital mortality after AAA repair, using two thirds of the available data. Model performance was then assessed on the remaining third of the data by receiver operating characteristic curve analysis and compared with existing risk prediction models. Model calibration was assessed by Hosmer-Lemeshow analysis.

Results: A total of 8088 AAA repair operations were recorded in the National Vascular Database during the study period, of which 5870 (72.6%) were elective procedures. Both preoperative and perioperative models showed excellent discrimination, with areas under the receiver operating characteristic curve of .89 and .92, respectively. This was significantly better than any of the existing models (area under the receiver operating characteristic curve for best comparator model, .84 and .88; $P < .001$ and $P = .001$, respectively). Discrimination remained excellent when only elective procedures were considered. There was no evidence of miscalibration by Hosmer-Lemeshow analysis.

Conclusions: We have developed accurate models to assess risk of in-hospital mortality after AAA repair. These models were carefully developed with rigorous statistical methodology and significantly outperform existing methods for both elective cases and overall AAA mortality. These models will be invaluable for both preoperative patient counseling and accurate risk adjustment of published outcome data.

Clinical outcomes of different approaches to aortic arch disease

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Objective: The aim of this study was to evaluate the midterm clinical outcomes of various approaches, including hybrid procedures, to aortic arch pathologies.

Methods: Of 305 consecutive patients who underwent aortic arch repair between 2005 and 2013, 244 underwent conventional open total aortic arch repair (CTAR) with antegrade cerebral perfusion under circulatory arrest, 35 underwent debranching of the arch with thoracic endovascular aortic repair (DTEVAR), and 26 underwent staged TEVAR after TAR with elephant trunk (TARET). We retrospectively evaluated the outcomes of the three groups.

Results: The DTEVAR group had a greater percentage of patients with preoperative comorbidities. Significant differences were observed in 30-day mortality (DTEVAR, 14.3% [5 of 35] vs TARET TEVAR, 0% [0 of 26] vs CTAR, 5.3% [13 of 244]; $P = .045$) and stroke (DTEVAR, 28.6% [10 of 35] vs TARET TEVAR, 7.7% [2 of 26] vs CTAR, 8.2% [20 of 244]; $P = .001$). In overall midterm survival, the DTEVAR group had a lower survival rate (63.9% 3-year survival) compared with the CTAR (90.1% 7-year survival) and the TARET TEVAR (95.5% 2.5-year survival) groups. In elective cases, better midterm results were observed in CTAR and TARET TEVAR groups. An increased number of debranching graft and emergency operations resulted in a much lower follow-up survival rate in the DTEVAR group. Atherosclerotic disease had a great effect on midterm outcomes in the DTEVAR ($P = .045$) and CTAR groups ($P = .002$).

Conclusions: The clinical feasibility of DTEVAR for high-risk patients requiring zone 0 landing or emergency surgery is still controversial. Atherosclerotic disease of the aorta has a significant negative effect on midterm outcomes in any surgical approach.

The impact of intraoperative shunting on early neurologic outcomes after carotid endarterectomy

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Background: Although the need for intraoperative shunting during carotid endarterectomy (CEA) is intensely debated, relatively few studies have compared the neurologic outcomes of patients undergoing CEA with or without shunts. The objective of our analysis was to determine the impact of intraoperative shunting during CEA on the incidence of postoperative stroke.

Methods: The 2012 CEA-targeted American College of Surgeons National Surgical Quality Improvement Program database was used for this analysis. The preoperative and operative characteristics of patients undergoing CEA with or without intraoperative shunting were compared. From this overall sample, propensity score techniques were then used to match patients with or without intraoperative shunting for a number of variables, including age, degree of ipsilateral and contralateral carotid stenosis, presence of several anatomic or physiologic risk factors, anesthesia modality, and use of patch angioplasty vs primary arteriotomy closure. The 30-day postoperative mortality and

combined stroke/transient ischemic attack (TIA) rates of this matched cohort were then compared. A similar analysis was also performed on a subgroup of patients with severe stenosis or occlusion of the contralateral carotid artery.

Results: A total of 3153 patients were included for initial analysis (2023 â no-shuntâ patients vs 1130 â shuntâ patients). From this overall sample, propensity score matching yielded a cohort of 1072 patients with or without intraoperative shunt placement who were well matched for all known patient- and procedure-related factors. There was no significant difference in the incidence of postoperative stroke/TIA between the two groups of this matched cohort (3.4% in the no-shunt group vs 3.7% in the shunt group; P = .64). Analysis of a similarly well matched subgroup of patients with severe stenosis or occlusion of the contralateral carotid artery demonstrated a statistically nonsignificant increase in the incidence of postoperative stroke/TIA with the use of intraoperative shunting (4.9% in the no-shunt group vs 9.8% in the shunt group; P = .08).

Conclusions: There is no clinical benefit to intraoperative shunting during CEA, even in patients who may be at high risk for intraoperative cerebral hypoperfusion due to severe stenosis or occlusion of the contralateral carotid artery.

Carotid artery stenting has increased risk of external carotid artery occlusion compared with carotid endarterectomy

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Objective: The external carotid artery (ECA) can be an important source of cerebral blood flow in cases of high-grade internal carotid artery stenosis or occlusion. However, the treatment of the ECA is fundamentally different between carotid endarterectomy (CEA) and carotid artery stenting (CAS). CEA is routinely associated with endarterectomy of the ECA, whereas CAS excludes the ECA from direct flow. We hypothesize that these differences make ECA occlusion more common after CAS. Further, the impact of CAS on blood flow into the ECA is interesting because the flow from the stent into the ECA is altered in a way that may promote local inflammation and may influence in-stent restenosis (ISR). Thus, our objective was to use our institutional database to identify whether CAS increased the rate of ECA occlusion and, if it did, whether ECA occlusion was associated with ISR.

Methods: Patients undergoing CAS or CEA from February 2007 to February 2012 were identified from our institutional carotid therapy database. Preoperative and postoperative images of patients who followed up in our institution were included in the analysis of ECA occlusion and rates of ISR.

Results: There were 210 (67%) CAS patients and 207 (60%) CEA patients included in this analysis. Despite CAS patients being younger (68 vs 70 years), having shorter follow-up (12.5 vs 56.2 months), and being more likely to take clopidogrel (97% vs 35%), they had an increased rate of ECA occlusion (3.8%) compared with CEA patients (0.4%). CAS patients who went on to ECA occlusion had an increased incidence of prior neck irradiation (50% vs 15%; P = .03), but we did not identify an association of ECA occlusion with ISR $>$50%.

Conclusions: Whereas prior publications have identified increased rates of external carotid stenosis, this is the first demonstration of increased ECA occlusion after CAS. However, ECA occlusion is uncommon (â¼4%) and did not have an association with ISR $>$50%. Future work modeling ECA flow patterns before and after CAS will be used to further test this interaction.

Statin therapy after infrainguinal bypass surgery for critical limb ischemia is associated with improved 5-year survival

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Objective: Although statin therapy has been linked to fewer short-term complications after infrainguinal bypass, its effect on long-term survival remains unclear. We therefore examined associations between statin use and long-term mortality, graft occlusion, and amputation after infrainguinal bypass.

Methods: We used the Vascular Study Group of New England registry to study 2067 patients (71% male; mean age, 67 $\pm$ 11 years; 67% with critical limb ischemia [CLI]) who underwent infrainguinal bypass from 2003 to 2011. Of these, 1537 (74%) were on statins perioperatively and at 1-year follow-up, and 530 received no statin. We examined crude, adjusted, and propensity-matched rates of 5-year surviva1, 1-year amputation, graft occlusion, and perioperative myocardial infarction.

Results: Patients taking statins at the time of surgery and at the 1-year follow-up were more likely to have coronary disease (38% vs 22%; $P < .001$), diabetes (51% vs 36%; $P < .001$), hypertension (89% vs 77%; $P < .001$), and prior revascularization procedures (50% vs 38%; $P < .001$). Despite higher comorbidity burdens, long-term survival was better for patients taking statins in crude (risk ratio [RR], 0.7; $P < .001$), adjusted (hazard ratio, 0.7; P = .001), and propensity-matched analyses (hazard ratio, 0.7; P = .03). In subgroup analysis, a survival advantage was evident in patients on statins with CLI (5-year survival rate, 63% vs 54%; log-rank, P = .01) but not claudication (5-year survival rate, 84% vs 80%; log-rank, P = .59). Statin therapy was not associated with 1-year rates of major amputation (12% vs 11%; P = .84) or graft occlusion (20% vs 18%; P = .58) in CLI patients. Perioperative myocardial infarction occurred more frequently in patients on a statin in crude analysis (RR, 2.2; P = .01) but not in the matched cohort (RR, 1.9; P = .17).

Conclusions: Statin therapy is associated with a 5-year survival benefit after infrainguinal bypass in patients with CLI. However, 1-year limb-related outcomes were not influenced by statin use in our large observational cohort of patients undergoing revascularization in New England.

Bone marrow aspirate injection for treatment of critical limb ischemia with comparison to patients undergoing high-risk bypass grafts

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Objective: Bone marrow cell therapy (BMCT) for patients with critical limb ischemia (CLI) is a potential treatment in candidates with poor options for standard revascularization procedures. Whereas clinical trials are ongoing, there are few comparative data to assess its efficacy compared with bypass.

Methods: Patients with poor revascularization options underwent BMCT between 2011 and 2013. Outcomes were compared with those of a cohort of CLI patients undergoing infrainguinal bypass thought to be at high risk for graft failure (tissue loss, a tibial target, and a previous endovascular treatment or bypass). BMCT patients underwent harvest of bone marrow that was then concentrated and injected intramuscularly into the ischemic limb.

Results: There were 20 BMCT patients and 35 high-risk bypass patients. All BMCT patients had either rest pain (80%) or tissue loss (80%). The majority (65%) had a prior intervention (bypass, 30%; endovascular, 58%) compared with high-risk bypass patients, all of whom had previous revascularization attempts (bypass, 43% [P = .35]; endovascular, 77% [P = .14]). Mean follow-up was 773 days after BMCT and 972 days after high-risk bypass. All patients tolerated BMCT without issues or complications. A second BMCT treatment was performed in 21% because of clinical deterioration. Wound healing occurred in 75% at 1.5 years, including patients receiving second injections, all of which resolved. Rest pain improved in 87.5% of patients. Pain completely resolved in 58% at 1.5 years. Ankle-brachial index improvement was 0.23 ($\pm$0.25). Three BMCT patients went on to amputation. One-year freedom from major amputation or death was 78% for BMCT vs 69% for high-risk bypass (P = .60).

Conclusions: BMCT is a potential option in CLI patients who are not candidates for bypass or endovascular intervention. Limb salvage is unexpectedly high in this population with few other options.